4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-2029]

Proposal To Withdraw Approval of MAKENA; Hearing; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of hearing; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice entitled "Proposal To Withdraw Approval of MAKENA; Hearing" that appeared in the *Federal Register* of August 17, 2022. The document announced the hearing on the Center for Drug Evaluation and Research's proposal to withdraw approval of MAKENA (hydroxyprogesterone caproate injection, 250 milligrams per milliliter, once weekly), new drug application 021945, held by Covis Pharma Group/Covis Pharma GmbH. The document was published with an incorrect deadline. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993, 240-402-5931, rachael.linowes@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of August 17, 2022 (87 FR 50626), in FR Doc. 2022-17715, on page 50628, the following correction is made:

1. On page 50628, in the last paragraph of the second column, in the first sentence, "September 6, 2022" is corrected to "September 14, 2022."

Dated: September 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-19293 Filed: 9/6/2022 8:45 am; Publication Date: 9/7/2022]